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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/671,995	09/29/00	CHARI	R 104322.198 U

024395                    HM12/0530  
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EXAMINER	
TRAN, M	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/671,995	CHARI, RAVI V. J.
	Examiner	Art Unit
	MAU T TRAN	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 April 2001.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 40-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims 40-89 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)      18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)      19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      20) Other: \_\_\_\_\_

### **DETAILED ACTION**

1. An election to the restriction requirement was made to Group III (claims 40 and 41) was noted in Paper #6. Applicant request the rejoinder of Group I (claims 1-32) with Group III. This request is denied as the Invention of Groups I and III are related as product and a method of use. However, the Invention of Group III does not have to be used to treat cancer as claimed in Group I. The Invention of Group III can be used to detect other proteins or to label cells. The restriction requirement is deemed proper and is made Final.
2. Claims 33-39, 42-43 have also been cancelled as noted in Paper #6 and new claims 44-89 have been added. However, these new claims must be restricted because they are drawn to distinct products as shown below.

#### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 40-45, 66-67, 48-53, 70-75, 54-58, 76-80 and 88-89, drawn to an anti-mitotic agent of maytansinoid, an antibody and one chemotherapeutic agent taxane.
  - II. Claims 40-45, 66-67, 48-53, 70-75, 59-62, 81-84 and 88-89, drawn to an anti-mitotic agent of maytansinoid, an antibody and one chemotherapeutic agent of platinum compound.
  - III. Claims 40-45, 66-67, 48-53, 70-75, 63-64, 85-86 and 88-89, drawn to an anti-mitotic agent of maytansinoid, an antibody and one chemotherapeutic agent of camptothecin compound.
  - IV. Claims 40-45, 48-53, 66-67, 70-75, 65 and 87 and 88-89, drawn to an anti-mitotic agent of maytansinoid, an antibody and one chemotherapeutic agent of an inhibitor of DNA topoisomerase I compound.
  - V. Claims 40-41, 46-47, 68-69, 48-53, 70-75, 54-58, 76-80 and 88-89, drawn to an anti-mitotic agent of Vinca, an antibody and one chemotherapeutic agent taxane.

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- VI. Claims 40-41, 46-47, 68-69, 48-53, 70-75, 59-62, 81-84 and 88-89, drawn to an anti-mitotic agent of *Vinca*, an antibody and one chemotherapeutic agent of a platinum compound.
- VII. Claims 40-41, 46-47, 68-69, 48-53, 70-75, 63-64, 85-86 and 88-89, drawn to an anti-mitotic agent of *Vinca*, an antibody and one chemotherapeutic agent of a camptothecin compound.
- VIII. Claims 40-41, 46-47, 68-69, 48-53, 70-75, 65, 87 and 88-89, drawn to an anti-mitotic agent of *Vinca*, an antibody and one chemotherapeutic agent of an inhibitor of DNA topoisomerase I.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different anti-mitotic agents and different chemotherapeutic agents which have different functions and chemical and physical structures.

The original claims 40-41 are drawn to a composition comprising at least one anti-mitotic agent, one immunoconjugate which is comprised of one antibody (binding agent) and one chemotherapeutic agent. Applicant is to select the composition as restricted above for examination on the merits.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mau Tran, whose telephone number is (703) 605-1165. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 5:30 p.m. with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Mau Tran, Ph.D.,  
Patent Examiner, Art Unit 1642  
May 16, 2001

  
GEETHA P. BANSAL  
PRIMARY EXAMINER